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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,424	11/24/2003	Sang-Wha Lee	NEIT0018	6330

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,424	LEE ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *5-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/21/04; 11/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-12 and 19 drawn to Sequence IDs 1 and 8 in the reply filed on 2/16/2006 is acknowledged. The traversal is on the grounds that there is no serious burden on the office to search ten of the fourteen sequences in the elected claims.

This is not found persuasive because searching more than one patentably distinct sequence represents a serious burden for the office because each sequence is drawn to a structurally distinct chemical compound. The search for ten sequences is a burden on the office because of the time it takes to fully search even one sequence.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 13-18 are withdrawn from consideration as being drawn to a nonelected group.

4. Claims 5-12 of Group 1 are also withdrawn from consideration as being drawn to nonelected primer pair sequences. Accordingly an action on the merits of Claims 1-4 and 19 directed to the primer pair of Seq ID No 1 and 8, is set forth below.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

Claims 1-3 are drawn to a sequence which is "fully complementary" to SEQ ID 1 or a sequence which is "fully complementary" to SEQ ID 8. The instant specification provides no guidelines as to what is encompassed by a sequence which is "fully complementary" to SEQ ID No. 1 or "fully complementary" to SEQ ID NO. 8. Broadly interpreted this could mean a sequence which is only a fragment of SEQ ID No. 1 or 8 but which complements fully. Brennan teaches every possible permutation of a 10-mer oligonucleotide (see Column 9, lines 53-55). Therefore, since Brennan teaches every possible combination of a 10 mer, Brennan inherently teaches 10mer combinations which are "fully complement" SEQ ID NO 1 and SEQ ID No. 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 3, 4, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gravitt et al (Journal of Clinical Microbiology January 2000 Vol 38 p. 357) in view of Chan et al (Journal of Virology May 1995 Vol 69 p. 3074) and Gelfand et al (US Patent 5487972 January 30,1996).

Gravitt et al. teaches the improvement of consensus PCR primers to detect a wide variety of HPV genotypes. Gravitt et al teaches primers designed in a conserved region of the L1 open reading frame can be used to detect various genotypes of HPV (p. 357 2nd column 1st paragraph). Gravitt et al teaches the L1 region of all sequence HPV genotypes was used to design primers (p. 358 Materials and Methods HPV sequence alignment and primer design). Gravitt et al teaches in designing primers, the efficiency of amplification is related to the number, position, and stability of a mismatch (p. 358 Results 1st paragraph). Gravitt et al. teaches primers with greater than four mismatches were less efficient (p. 358 Results 1st paragraph). Gravitt et al. teaches primers with less than four mismatches overall but with one or more mismatches at the 3' end of the oligonucleotide were less efficient (p. 358 Results 1st paragraph). Gravitt et al teaches that the concentration of magnesium chloride in the PCR assay would effect the ability of primer pairs to detect genotypes (p. 358 Results last sentence and first sentence of p. 359). Gravitt et al teaches the use of primers designed to nondiscriminately amplify any genital HPV type present in a reaction mixture (p. 361 2nd

paragraph). With regard to Claim 19, Gravitt et al. teaches the use of a PCR assay comprising primers, a mixture of dNTPs, taq polymerase, and a PCR buffer.

Gravitt et al., however, does not teach the alignment of other genes of HPV genotypes or guidance in choosing primers which have been designed.

Chan et al teaches the phylogenic relationship of all known papillomaviruses and a database which encompasses HPV-1 to HPV-73 (Abstract). Chan et al. teaches that a new HPV genotype is one that has at least 10% dissimilarity in the combined nucleotide sequences of the E6, E7, and L1 genes when compared with known genotypes (p. 3074 2nd column 1st paragraph). Chan et al teaches the sequencing of 2.4 kb or the genome of all new isolates and sequence alignment (p. 3074 2nd column 1st paragraph). Chan et al teaches the alignment of several genomic segments among all known PV genomes (p. 3075 2nd column Results 1st paragraph). Chan et al teaches the alignment of the amino acid sequences, which correspond to the L1 gene of 92 PV types (p. 3075 2nd column Results 2nd paragraph and Figure 1).

Gelfand et al. teaches a process of detecting a target nucleic acid using primers and probes in a PCR amplification assay (abstract). Gelfand et al. teaches a method comprising providing a set of oligonucleotide primers and amplifying the target nucleic acid sequence in a PCR reaction annealing both the primers and a labeled probe, and detecting the release of labeled fragments to determine the presence or absence of target sequences in the sample (column 2, lines 46-67 and column 3 lines 1-10).

Gelfand et al. provides guidance in the choosing of primers.

"The primer must be sufficiently long to prime the synthesis of extension products in the presences of the agent for polymerization. The exact length and composition of

the primer will depend on many factors, including temperature of the annealing reaction, source and composition of the primer, proximity of the probe annealing site to the primer annealing site, and ration of primer: probe concentration. For example, depending on the complexity of the target sequence, the oligonucleotide primer typically contains about 15-30 nucleotides, although a primer may contain more or fewer nucleotides. The primers must be sufficiently complementary to anneal to their respective strands selectively and form stable duplexes" (Column 8 lines 21-34).

With regard to Claim 19, Gelfand et al. teaches a kit which includes primers, suitable packaged reagents and materials needed for amplification, buffers, and dNTPs (Column 14, lines 5-10).

Therefore, the ordinary artisan would have been motivated to select any number of primers including SEQ ID Nos. 1 and 8 for amplifying a region of HPV which could be use to identify a large number of genotypes of HPV. The art of designing primers at the time the invention was made was very well described in the art. The art uses alignment programs to align sequences of interest and then uses algorithms to select and test primers for their desired function of either detecting or distinguishing particular organisms. Designing primers, which are equivalents to those taught in the art, is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as primers, see Gelfand et al. Moreover there are many Internet web sites that provide free downloadable software to aid in the selection of primers drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design primers. The claimed primers are prima facie obvious over the cited references in the absence of secondary considerations, given the extensive teachings in the art. It would have been prima facie

obvious to one of ordinary skill in the art at the time the claimed invention was made to use the multiple alignment and oligonucleotides taught by Gravitt et al. and Chan et al. to create new primers and using the guidance of the design constraints of primers taught by Gelfand et al. to obtain equivalent alternative primers of the claimed invention. The ordinary artisan would be motivated to have designed and test new primers to obtain additional oligonucleotides that function to detect HPV genotypes and identify oligonucleotides with improved properties.

Conclusion

6. No Claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 3/17/2006
Katherine Salmon
Examiner
Art Unit 1634

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JEHANNE SITTON
PRIMARY EXAMINER
3/20/06